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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,945	11/13/2001	Juan Mantelle	041457-0633	6420

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EXAMINER	
BERKO, RETFORD O	
ART UNIT	**PAPER NUMBER**
1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/986,945	Applicant(s) MANTELLE ET AL.	
	Examiner Retford Berko	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) 1-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Acknowledgement: Information Disclosure Statement filed November 13, 2001 is acknowledged.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-6, 14-17 and 21-25 of U.S. Patent No. 6, 316, 022. This is a provisional obviousness-type double patenting rejection. Although the conflicting claims are not identical, they are not patentably distinct from each other because: (a) the scope of applicant's claims teach a pressure-sensitive transdermal drug delivery system comprising a blend of polymers and one or more drugs, the polymers being of high shear resistant acrylic-based, molecular weight equal to 600,000 to 1,000,000 daltons (resistance greater than or equal to 100 hrs at 4 lbs/sq in). (b) the polymer is about 10-90 wt/% of the composition (c) the drug is nicotine and can be in combination with other drugs (d) a method of making the composition is taught.

3. The scope of claims 1-6, 14-17 and 21-25 in Patent '022 teaches polymer-based trnasdermal compositions containing low molecular weight drugs at least one of which is liquid at room temperatures.

(c) Patent '022 specifically taught that one of the polymers in the invention could be acrylic based having shear resistance as claimed by the present applicant, that the polymer has average molecular weight of 600-1,000.000 daltons and one drug used in the composition was nicotine (col 15, lin 20-45). The method of making the composition is taught in claims 23-25 of Patent '022 (col 17 through col 18).

4. The examiner considers that physical parameters such as shear resistance, number of hours pertaining to shear resistance and temperature, low molecular weight , shape and size herein claimed constitute apparent manipulations to one of ordinary skill in the art. With respect to these manipulations, it has been held that where general conditions of the claims are disclosed by the prior art, determining the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 U.S.P.Q. 233.

5. Patent '022 teaches that the adhesives of the transdermal drug delivery system could be formulated at temperatures that give desirable characteristics for adhesives used in the transdermal delivery art (col 7, lin 55-60),varying the amount of monomers used in the polymer would change the cohesive properties of the polyacrylate-based polymer consistent with what is known in the art (col 8, lin 20), that transdermal delivery system can be in any shape or size as is necessary or desirable (col 10, lin 30-35). Patent '022 teaches that the use of high shear resistant polymers increased ability for solubilization of the drug in the polymer matrix of the trandermal drug delivery device, that the selection of suitable polymer can be determined by one of ordinary

skill in the art and that the shear resistance of the polymer is generally related to the molecular weight of the polymer. Patent '022 teaches a general method of preparation of the composition not unlike what applicant claimes in the present application.

One of ordinary skill would be motivated to modify the physical parameters of the formulation, specifically such as the shear resistance and molecular weight or the nature of the drug or its amount when formulating the composition in order to obtain desirable characteristics.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claim 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Miranda et al (US5, 656, 286).

2. Patent '286 teaches a pressure-sensitive trnasdermal drug delivery system comprising a blend of two or more polymers in combination with a drug e.g. nicotine (abstract, col 6, lin 30, col 58, example 81 and col 60, lin 50).

3. As in applicant's claims 2, Patent '286 teaches acrylic-based polymers for making the composition (col 9, lin35-40, col 10, lin 45, col 38, lin 60, col 45-46, col 47, lin 60-65).

4. As in applicant's claims 3-15, Patent '286 taught that a transdermal drug delivery system that was pressure-sensitive (abstract, col 34, lin 30 and col 61, lin 15-40).

5. Applicant's process or methods of producing pressure-sensitive transdermal drug delivery composition –producing a blend of polymer, drug and solvent as claimed in claims 17-21, are taught in Patent '286 (col 35, lin 15-20 and col 65, lin 30).

Claim Rejections-35 USC Sec. 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The relevant part of the factual inquiries set forth in Graham v. John Deere & Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue
3. Resolving the level of ordinary skill in the pertinent art
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

7. Claims 1-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miranda et al (US5, 656, 286) in view of l (US 5, 474, 783) further in view of Horstmann et al (US 5, 230, 898).

8. The scope of applicant's claims teach a pressure sensitive transdermal drug delivery composition wherein applicant claims that the delivery system comprises of a blend of acrylic polymers having shear resistance of 50 hours at 8 lbs/sq in and 72 degrees F or shear resistance greater than 100 hours at 8 lbs/sq in and 72 degrees F. According to applicant's claims, the drug is present in the composition at 1-40 wt/% and the molecular weight of the polymer ranges from

600, 000 to 1, 000,000 daltons. Applicants's claims further teach a method of producing the formulation entailing blending of polymers, drug and solvent. The specification describes various examples of polymer components that applicant used in order to achieve the composition characteristics claimed in the invention and commercial nomenclature for the polymers (see pages 20-21, tables 1-3).

9. As discussed above, Patent '286 teaches a blend of at least two polymers in combination with a drug (s) such as nicotine for transdermal delivery in a pressure-sensitive adhesion composition (abstract). Patent '286 teach the use of commercial polymers for formulating the composition equivalent to what applicant used (e.g. polymethacrylate, col 8, table 1A; Bio-PSA X7-4503, col 47; Duro-Tak 80-1196; col 53) as well as the disclosure of other polymers with molecular weight less than 2,000,000 (col 3, lin 10). Patent '286 teaches that multiple polymer adhesives not only functions as a carrier matrix for the drug, but enhances the rate of release of the drug and hence the transdermal permeation rate (col 7, lin 5). Patent '286 further teaches the process for formulating the composition equivalent to what applicant claims (seel col 35, lin 15-20 and col 65, lin 30 continuing to col 65). Patent '286 does not teach the pressure-sensitive transdermal drug delivery system in the composition nor the exact polymers with molecular weights ranging from 600,000 to 1, 000,000 daltons, shear resistance of 100 and above at 8 lbs/sq in at 72 degrees F.

10. Patent '783 teaches the use of Bio-PSA X7-3027, polyacylate adhesive and Duro-Tak 80-1194 polymers in combination with drugs for forming transdermal drug delivery composition (col 16, lin 5-55). Patent '783 further teaches that dermal compositions using these polymers can be produced by a variety of methods known in the preparation of drug-containing adhesive

preparations that can be adjusted to obtain delivery rates of drug while maintaining acceptable shear, tack and peel adhesive properties (abtract).

11. One of ordinary skill in the art would be motivated to use different polymers combinations, drug (e.g. nicotine) in place of the nitroglycerine used by Miranda et al (Patent '783) in amounts that would produce a dermal formulation that has pressure sensitive adhesive properties and shear resistance as claimed by applicant. One of ordinary skill would expect to obtain desirable rnasdermal permeation rate of the drug. Therefore, the invention as a whole would have been prima facie obvious at the time applicant made her invention.

12. The scope of the disclosure in Horstmann et al (Patent '898) wherein a transdermal drug delivery system comprising basic polymers such as polyacrylic acid ester containing nicotine (col 3, lin 45 continuing through col 4, lin 40) teach that the transdermal drug delivery composition exhibits pressure-sensitive adhesive properties, as claimed by applicant. One of ordinary skill in the art would be motivated to use different combinations of polymers and drugs that give formulations with desirable shear, tack and peel characteristics as claimed by applicant. One of ordinary skill would expect to obtain transdermal drug delivery system having uptimal dermal permeation rate for the drug to be delivered. Therefore, the invention as a whole would have been prima facie obvious at the time applicant made her invention

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Retford Berko whose telephone number is 703-305-4442. The examiner can normally be reached on M- F 8:00a.m-5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9903 for regular communications and 703-746-9903 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

ROB
December 13, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600